K081537

Grass Technologies, An Astro-Med, Inc. Product Group
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5. 510(k) Summary

DEC 24 2008

Submission Date: June 2, 2008

Submitted by: Grass Technologies, an Astro-Med, Inc. Product Group
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Contact Person: Alfredo Bustamante
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Proprietary Name: TWin Neurotrac-III

Common/Usual Name: Electroencephalography (EEG)

Product Classification:
Category: Electroencephalograph
Regulation Number: 882.1400
Product Code: OMA, OLT, ORT
Product Class: Class II

Substantial Equivalent Predicate Devices:

- **Neurotrac II-EP, 510(k) #K960170,** Moberg Medical, Inc., Purchased by Astro-Med, Inc.
- **Neurotrac II, 510(k) # K914571,** Moberg Medical, Inc., Purchased by Astro-Med, Inc.
- **Nervus Monitor, 510(k) # K021185,** Taugagreining HF, now Nicolet Biomedical, a Viasys Healthcare/Cardinal Health Brand
- **Olympic CFM6000, 510(k) # K031149**, Olympic Medical Corp, now a division of Natus Medical Inc.
- **BRM3 Brain Monitor, 510(k) #K071449,** BrainZ Instruments LTD., Auckland, New Zeland

Device Description:
TWin Neurotrac-III is used with Grass-Technologies TWin (#K012976) EEG Recording and Review systems for displaying and recording long term trends of EEG features during continuous EEG monitoring in the ICU, NICU, OR, EEG/PSG laboratories, and/or inpatient long-term seizure monitoring units. TWin Neurotrac-III can be used with EEG acquisition systems configured with any of Grass-Technologies' amplifiers, including AS40 (#K021807), AURA (#K033978), AURA-LTM64 (#K053606) and Beehive (#K884937) amplifiers. The number of EEG channels recorded is dependent on the amplifiers used, the number of electrodes applied to the patient, and the user selected EEG display montage. In addition to displaying and recording the EEG waveforms, TWin Neurotrac-III can also display and record trends of user selectable EEG features to facilitate viewing changes in the EEG over prolonged periods of time. The number and type of trends, and the EEG channels processed are selected by the user.

Indications for Use:
The intended use for TWin Neurotrac-III is to record the electroencephalogram (EEG) and the computed EEG trends over extended periods of time in order for trained health care professionals to observe changes over time. TWin Neurotrac-III does not provide any diagnostic conclusion about the patient's condition.

TWin-Neurotrac-III is intended for use only by medically trained and qualified personnel, within a hospital or medical environment.

Summary of Comparison to Predicate Devices:
In general, TWin Neurotrac-III and the predicate devices are similar in features and technical characteristics. There are no major differences that would alter intended use or jeopardize patient safety. TWin Neurotrac-III and the predicate devices have the same indication of use: to record and process EEG signals to monitor the state of the patient's brain; for use by medically trained and qualified personnel; for use in various areas of the hospital or medical institution; and for use with patients in all age groups.

Twin Neurotrac-III and all predicate devices display and record raw EEG waveforms, as well as processed EEG data to facilitate viewing changes in the EEG over prolonged periods of time. All devices use computer software for displaying, recording, and processing EEG data. TWin Neurotrac-III and the predicate devices are not life supporting or life sustaining devices, and no claims are made that the device is in and of itself diagnostic.

The only significant difference between TWin Neurotrac-III and the predicate devices is the number of EEG channels displayed, processed, and recorded: predicate devices Olympic CFM6000 and BRM3 Brain Monitor record 2 and 3 channels; predicate devices Neurotrac II and Neurotrac II-EP record up to 8 channels; predicate device Nervus Monitor records 16 or 32 channels. TWin Neurotrac-III can process up to 16 user selected channels, and the total number of raw EEG channels recorded and displayed is a function of the Grass Technologies amplifiers used as listed in the above device description (up to 128 channels), the number of electrodes applied by the user, and the selected display montage. With TWin Neurotrac-III, the number of raw EEG channels and processed channels displayed and recorded is defined by the user. Another difference is that predicate device Neurotrac II-EP can monitor evoked electrical activity (EPs) in addition to EEG. TWin Neurotrac-III does not monitor Evoked Potentials and no claims are made that it can. Excluding the Evoked Potentials function, Moberg's Neurotrac II predicate devices are the basic foundations for TWin Neurotrac-III's EEG display, recording and processing function.

Non-Clinical Testing:
In house testing using simulated signals, as well as real EEG from previously recorded studies show that TWin Neurotrac-III meets design and performance functional requirements. Testing has also shown that TWin Neurotrac-III does not adversely alter the functionality of the TWin software, it does not alter the functionality of the EEG amplifiers used, it does not jeopardize the safety of the patient connected to the EEG amplifiers, nor does it jeopardize the safety of the operator.

Beta Site Testing:
Testing of TWin Neurotrac-III was performed at Beta sites under the supervision of qualified medical personnel. This testing showed that TWin Neurotrac-III meets design and performance functional requirements. Testing has also shown that TWin Neurotrac-III does not adversely alter the functionality of the TWin software, it does not alter the functionality of the EEG amplifiers used, it does not jeopardize the safety of the patient connected to the EEG amplifiers, nor does it jeopardize the safety of the operator. No clinical testing was necessary to demonstrate substantial equivalence for this product.

Conclusion Demonstrating Safety, Effectiveness, and Performance:
The testing carried out for the TWin Neurotrac-III indicates that it meets design and performance functional requirements. When used with TWin software ((#K012976) and Grass Technologies EEG amplifiers [AS40 (#K021807), AURA (#K033978), AURA-LTM64 (#K053606, Beehive (#K884937)], TWin Neurotrac-III is equivalent to the predicate devices in terms of safety, effectiveness, and performance. TWin Neurotrac-III can not be used with any other company's software and EEG amplifiers.

Alfredo Bustamante
Product Manager
Grass Technologies, an Astro-Med, Inc. Product Group

06/02/08
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ASTRO-MED INC.
c/o Mr. Alfredo Bustamante
600 East Greenwich Ave
West Warwick, RI 02893

Re: K081551
Trade/Device Name: Twin Neurotrac-III
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OMA, OLT, ORT
Dated (Date on orig SE ltr): December 10, 2008
Received (Date on orig SE ltr): December 15, 2008

APR - 9 2012

Dear Mr. Bustamante:

This letter corrects our substantially equivalent letter of December 24, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Jessica Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K081551

Device Name: TWin Neurotrac-III, Grass-Technologies, an Astro-Med, Inc. Product Group

Indications for Use:

The intended use for **TWin Neurotrac-III** is:

To record the electroencephalogram (EEG) and the computed EEG trends over extended periods of time in order for trained health care professionals to observe changes over time. **TWin Neurotrac-III** does not provide any diagnostic conclusion about the patient's condition.

TWin-Neurotrac-III is intended for use only by medically trained and qualified personnel, within a hospital or medical environment.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081551